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| 10/751,276 | 01/02/2004 | Sebastiano Scarampi | 033292-004 | 7478 |
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| EXAMINER | | | | |
| GHALL, ISIS A D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1611 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 04/09/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary**Application No.**

10/751,276

Applicant(s)

SCARAMPI ET AL.

Examiner

Isis A. Ghali

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 6-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and terminal disclaimer, both filed 01/11/2008.

Claims 1-36 are pending.

1. This application contains claims 6-16 drawn to nonelected invention with traverse and claims 17-36 drawn to nonelected inventions without traverse in the reply filed on 05/11/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-5 are included in the prosecution.

Terminal Disclaimer

2. The terminal disclaimer filed on 01/11/1008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending applications serial numbers 10/887,466 and 10/887,453 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following new ground of rejections is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5 rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,001,688 ('688) in view of US 7,074,392 (392).

CA '688 teaches topical composition for treating human nails comprising 6.25% Gilsonite, mineral oil carrier, preservative, and 3% of soybeans that reads on the bioactive agent (page 3, 1st paragraph; page 5, 3rd full paragraph; page 6, 1st paragraph;

page 8, 2nd and 4th paragraphs). CA '688 further teaches the composition further comprising antibacterial and antifungal agents (page 3; page 5, last paragraph).

Although CA '688 suggested bioactive agents including antibacterial agent in the composition applied to the nails, however, does not explicitly teach hydrocortisone, nicotine, or caffeine as instantly claimed by claim 1.

US '392 teaches sustained release nail treating composition comprising antibacterial agents and antipsoriatic agent, with hydrocortisone is preferred antipsoriatic agent in an amount of 0.1-10% (abstract; col.3, lines 36-39; col.4, lines 46-50; col.14, lines 45-49). The composition is suitable to treat nail and surrounding tissues and it reduces the unwanted side effects caused by high concentration of the antimicrobial agents (col.3, lines 24-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical composition for treating human nails comprising Gilsonite and antimicrobial agent as disclosed by CA '688, and further add hydrocortisone to the antimicrobial agent or replace antimicrobial agent with hydrocortisone according to the condition to be treated because US '392 disclosed that antimicrobial agents can be administered with hydrocortisone to the nails and further teaches that hydrocortisone is one of the preferred active agents to treat psoriasis of the nails and surrounding tissues and composition comprising hydrocortisone reduces the unwanted side effects caused by high concentration of the antimicrobial agents, with reasonable expectation of having topical composition for treating human nails

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comprising Gilsonite and antimicrobial agent and/or hydrocortisone that successfully treats the nail and surrounding tissues without any unwanted side effects.

Response to Arguments

6. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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